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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,331	05/30/2001	Charles E Martin	13259-00008	4826

7590 08/13/2003

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/763,331

Applicant(s)

MARTIN ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 15 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-20 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

Claims 1-5 and 7-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell A. *et al.* J. of Biol. Chem., December 15, 1995; vol. 270, No. 50; pp. 29766-29772 in view of Fischhoff D. *et al.* U.S. Patent 5,500,365 published March 19, 1996. This rejection is maintained for the reasons of record set forth in the Official action mailed 01/15/2003.

Applicant's arguments filed 5/15/2003 have been considered but are not deemed persuasive.

Applicant asserts that the Examiner's characterization of Mitchell as teaching that "inherent placement of a heterologous cytochrome b5 domain thus teaching what the replacement of the native cytochrome b5 should be" is unclear, and that they refrained from addressing this point (response page 8). The Examiner will attempt to clarify; the reference teaches a native  $\Delta 9$ /cyt-b5 enzyme from yeast and thereby teaches a sequence that may be optimized for expression in plants that reads upon the invention as broadly claimed.

Applicant asserts that the Examiner's allegation that optimization of a genetic sequence is based upon their disclosure, and that prior art is required to suggest otherwise and is also required to suggest that the choice of a promoter of a gene encoding an ER biosynthetic enzyme to express fatty acid desaturase is an obvious design choice (response page 9). It is well known in the art that exogenous proteins are best expressed in plants when their codons are optimized for plant expression needs no further elucidation. Further, it is also well known in the art that the endoplasmic reticulum of a plant is where much of fatty acid biosynthesis occurs. Applicant's attention is directed to pages 2-4 of the specification where this issue is discussed (i.e. the

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activity of cytochrome b5); see Strittmatter and Rogers, Somerville and Browse and the references cited in Table 1 on page 4. Also, see *In re Kuhle*, 188 USPQ 7, (CCPA 1975), which teaches that a feature which solves no stated problem and which presents no unexpected results would have been an obvious matter of choice.

Applicant asserts that the Fischhoff reference does not teach optimization of catalytic proteins and since the present invention is not the mere optimization of a structural protein the Fischhoff reference does not teach any motivation to optimize a catalytic protein or any expectation of success in doing so. Applicant further asserts that the Mitchell reference does not teach but is rather an invitation to experiment and thus teaches away from using these proteins in systems where the effects on electron transport are unknown (response pages 10-12). Applicant's evidence of successful electron transport following modification of the gene sequence, as stated on page 12 of the response were unexpected ("the advantages of a bifunctional desaturase were not expected") and only obtained by the modification of a single yeast polynucleotide encoding a bifunctional desaturase. Further, these unexpected results are not reflected in the features of the claims other than Claim 6 which is limited to the sequence that provided the unexpected results i.e. successful electron transport in *Arabidopsis*. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In contrast, the claims are broadly drawn to a multitude of sequences from a multitude of sources, including animal or plant genes encoding a non-functional desaturase, and their optimization for a multitude of plant species. See *In re Lindner*, 173 USPQ 356 (CCPA 1972)

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and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Applicant asserts that it was not appreciated that optimizing expression of non-plant desaturases as well as intracellular protein targeting and or enzyme stability would yield advantages (response page 13). See arguments as discussed above regarding claim breadth versus evidence of unexpected results.

### ***Claim Rejections - 35 USC § 112***

Claims 1-5 and 7-20 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant asserts that they have provided sufficient identifying information for at least four additional sequences and two partial sequences for bifunctional desaturase/cyt b<sub>5</sub> enzymes and that these sequences are described in Figure 1 and on page 14, i.e. Accession numbers to polynucleotides known to encode Fungal bifunctional Ole1 enzymes, and since the sequences are well characterized with respect to the written description requirements, Applicant is in possession of the claimed invention (response pages 15-17). The specification on pages 49-53 only describes proteins, not genes, and Figure 1 only references fungal species known to have bifunctional proteins, and as such no guidance was provided for identifying any other bifunctional sequences from any other non-fungal source or for modification of gene sequences. Further, the only exemplified species was a bifunctional enzyme from yeast and the second

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sequence disclosed on page 43 of the specification is from the same source. Applicant admits that this type of desaturase has only been found or observed in Fungi, and since there is insufficient description for the invention encompassing a fatty acid desaturase comprising a desaturase domain and a cytochrome b<sub>5</sub> domain customized for expression in a plant cytoplasm, Applicant is not in possession of the broadly claimed invention.

Claims 1-5 and 7-20 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-5 and 7-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modified fungal bifunctional desaturase/cyt b<sub>5</sub>, OLE1 genes, does not reasonably provide enablement for a modified bifunctional desaturase/cyt b<sub>5</sub> from any source other than a fungal source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant asserts that the claims are fully enabled by the entire specification (response page 18); the Examiner should construe the claims to find any material in the claims that is enabling (response page 18), and have noted that it is not clear whether any claim scope has been identified in the Office Action (response page 20). This issue has been addressed above.

Applicant asserts that Mazier and Iannocone do not address the unpredictability in the art of gene modification in view of the Fischhoff Patent, and that problems in optimizing gene expression encountered by Mazier and Iannocone were due to impurities in the oligos or the

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fidelity of the polymerase used (response pages 20-22). The Examiner acknowledges Applicant's arguments with respect to making synthetic sequences and the effect contaminated or imprecise materials can have, but points out that those problems were not eliminated and were only marginally reduced when better materials were used. The Examiner respectfully submits that although one of skill in the art can make alterations to DNA sequences, as Applicant has pointed out with respect to the references cited in the last office action, that success is dependent upon whether there is adequate description for making such changes. When considering that Applicant has acknowledged the unexpected discovery of electron transport following alteration of the fungal gene sequence as discussed above, and the unpredictability stated above and in the references from the last office action, Applicant has not provided guidance as to which residues from any one of the broadly claimed non-exemplified sequences when expressed in a multitude of non-exemplified plant species other than *Arabidopsis*, when changed would be permissive of bifunctional desaturase/cyt b<sub>5</sub> activity. With respect to the allegedly inconsistent rejections under 35 U.S.C. 112 and 35 U.S.C. 103, the Examiner maintains that the test for adequacy of a prior art disclosure to anticipate or render claims obvious is not the same test as that for adequacy of a patent application disclosure to support claims under 35 U.S.C. 112, as taught in *In re Hafner*, 161 USPQ 783, (CCPA 1969).

Claims 1-5 and 7-20 remain rejected.

Claim 6 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.  
August 11, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~480~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a stylized flourish at the end.